UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois corporation, Plaintiff, v. BANNER PHARMACAPS, INC., a Delaware corporation, Defendant.	Civil Action No. 07-CV-00754-GMS

BRIEF IN SUPPORT OF ABBOTT LABORATORIES'
MOTION TO DISMISS BANNER'S FIRST COUNTERCLAIM

Dated: August 8, 2008

CONNOLLY BOVE LODGE & HUTZ LLP
Paul E. Crawford
DE State Bar 0493
E-mail: pcrawford@cblh.com
1007 N. Orange St.
P.O. Box 2207
Wilmington, DE 19899
(T) 302.658.9141
(F) 302.658.5614

Attorneys for Abbott Laboratories

Of Counsel
Daniel E. Reidy; Bar No. 2306948
E-mail: dereidy@jonesday.com
James R. Daly; Bar No. 6181714
Email: jrdaly@jonesday.com
Jason G. Winchester; Bar No. 6238377
Email: jgwinchester@jonesday.com
Melissa B. Hirst; Bar No. 6282498
Email: mbhirst@jonesday.com
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601-1692
(T): 312.782.3939
(F): 312.782.8585

Perry C. Siatis
ABBOTT LABORATORIES
100 Abbott Park Road
Abbott Park, Illinois 60064-6034

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

I. NATURE AND STAGE OF PROCEEDINGS

Plaintiff, Abbott Laboratories ("Abbott"), initiated this lawsuit against Defendant, Banner Pharmacaps, Inc. ("Banner"), on November 21, 2007, in response to Banner's submission of New Drug Application No. 22-152 (the "NDA"). Banner's NDA sought FDA approval to market a proposed generic version of Abbott's Depakote® (divalproex sodium) before the expiration of two patents owned by Abbott: U.S. Patent Nos. 4,988,731 and 5,212,326 (collectively, the "Patents"). For this reason, Banner's submission of the NDA constituted a technical act of infringement of the Patents. (*See generally* Complaint (D.I. 1).) Banner answered the Complaint and asserted two counterclaims, including a claim seeking a declaratory judgment that its proposed generic product would not infringe Abbott's Patents. (*See* D.I.7.)[1]

The Patents expired on January 29, 2008, no longer posing any impediment to Banner's manufacture, use, or sale of its generic version of Depakote®. In light of the Patents' expiration, the FDA has formally approved Banner's NDA and Banner is about to launch its generic product. As such, there is no longer a live case or controversy before this Court regarding whether Banner's product does or does not infringe Abbott's Patents; that issue is undeniably moot. Recognizing this fact, Abbott approached Banner to seek agreement to a joint stipulation dismissing this action with prejudice. Banner refused, forcing Abbott to proceed by way of motion. Abbott moved for voluntary dismissal, with prejudice, of its own affirmative claims on July 28, 2008 (D.I.18), and now respectfully moves this Court, pursuant to Rule 12(b)(1), to dismiss Banner's non-infringement counterclaim as moot.[2]

---

[1] Banner's second counterclaim, styled as "unfair competition," is the subject of a separate motion to dismiss filed by Abbott, which has been fully briefed. (*See* D.I.11.)

[2] A conference is set for September 10, 2008 in this case, and Abbott will be prepared to address any questions the Court might have about this or any other pending motion at that time.

II. SUMMARY OF ARGUMENT

Banner's first counterclaim, which seeks a judicial declaration that the product described in Banner's NDA does not infringe the Patents, should be dismissed as moot, for two reasons.

1. *First*, Banner's non-infringement counterclaim is rendered moot by the expiration of the Patents and the FDA's final approval of Banner's generic product, Stavzor™. Absent a live case or controversy, Banner's counterclaim must be dismissed.

2. *Second*, as in all litigation arising under the Hatch-Waxman Act, this Court's subject-matter jurisdiction rests upon the presence of a so-called paragraph IV certification in Banner's NDA. Banner did submit such a certification (by which Banner attested that its product would not infringe Abbott's extant patents) in its NDA, so jurisdiction initially was proper. When Abbott's patents expired, however, Banner's paragraph IV certification converted automatically to a paragraph II certification, which cannot as a matter of law support Article III jurisdiction.

III. STATEMENT OF FACTS

A. Background Regarding The Hatch-Waxman Act And § 505(b)(2) New Drug Applications

The FDA maintains a list (called the "Orange Book") of all pharmaceutical drugs approved for sale in the United States. The Orange Book contains a variety of information about approved drug products and lists each patent that the manufacturer contends covers some aspect of the drug product. This information is regularly utilized by generic drug companies in seeking FDA approval of their products. Particularly important for purposes of this motion is the manner in which such information is used by an applicant (like Banner) seeking approval of a generic drug product pursuant to § 505(b)(2) of the Food Drug and Cosmetic Act.

An applicant submitting a § 505(b)(2) NDA is not required to conduct full clinical trials, in the way that an innovator company (like Abbott) must for a new drug product. Instead, a § 505(b)(2) applicant compares its generic product to an already-approved innovator product (called the reference-listed drug, or RLD), and relies upon all of the safety and efficacy studies conducted by the innovator in securing approval of the RLD. *See* 21 U.S.C. § 355(b). Pursuant to the Hatch-Waxman Act, the § 505(b)(2) applicant must review the Orange Book listing of the RLD it is relying upon, and must make one of four certifications as part of its application: (i) the innovator has not listed any patent information with FDA; (ii) any listed patent has expired; (iii) the listed patent expires on a date before which the § 505(b)(2) applicant is seeking to market its product; or (iv) the listed patent is invalid or will not be infringed by the manufacture, use, or sale of the drug described in the NDA. *See* 21 U.S.C. § 355(b)(2)(A)(i)-(iv).

An applicant that includes a "paragraph IV certification" in its § 505(b)(2) NDA is required to transmit notice of this certification to the patent holder, along with a detailed explanation of the legal and factual bases for the certification. *See* 21 U.S.C. § 355(b)(3). When the listed patents expire, an applicant's paragraph IV certification is converted to a paragraph II certification, and FDA is free to approve the generic product for marketing to the public. *See, e.g., Ranbaxy Labs. Ltd. v. FDA,* 307 F. Supp. 2d 15, 19 (D.D.C. 2004); 21 U.S.C. § 355(c)(3)(A).

B. Banner Chose Abbott's Depakote® As The Reference-Listed Drug For Its Proposed Generic Product And Submitted A Paragraph IV Certification Directed To Abbott's Patents.

Abbott's Patents cover divalproex sodium, the active ingredient in Abbott's widely-used anti-convulsive drug Depakote®, and are, therefore, listed in the FDA's Orange Book in association with that product. (Complaint (D.I. 1) ¶ 12; *id.* at Exs. A & B.) In October 2007, Banner notified Abbott that Banner had submitted NDA No. 22-152 under § 505(b)(2).

Although Banner characterized the active ingredient in its proposed product as valproic acid, the notice made clear that Banner did *not* select as its reference-listed drug one of the many FDA-approved valproic acid products. Instead, Banner elected Abbott's Depakote® product (which contains divalproex sodium as its active ingredient) as the proper RLD. Banner further indicated that its NDA contained a paragraph IV certification directed to Abbott's Patents (which cover divalproex sodium), and that Banner was seeking FDA approval to market its generic product before the Patents expired.

C. In Response To Banner's Paragraph IV Certification, Abbott Initiated This Lawsuit.

Pursuant to the Hatch-Waxman Act, Abbott had 45 days from receipt of Banner's notice to initiate a complaint for patent infringement. 21 U.S.C. § 355(c)(3)(C). Abbott met this deadline, filing suit on November 21, 2007. (*See* Complaint (D.I. 1).) Banner answered, denying infringement and lodging two counterclaims – one seeking a declaratory judgment of non-infringement and the other alleging "unfair competition." (*See generally* Answer & Counterclaims (D.I. 7).) Abbott previously moved to dismiss the unfair competition claim pursuant to Rule 12(b)(6), and that motion is fully briefed. (*See* Motion to Dismiss (D.I.11).)

D. Abbott's Patents Have Now Expired, And Banner's Generic Product Has Been Finally Approved By The FDA.

On January 29, 2008, Abbott's Patents expired. Because Abbott completed certain important studies relating to the administration of Depakote® to children, Abbott was awarded an additional period of regulatory exclusivity that extended through July 29, 2008. After that date, however, nothing about Abbott's Patents or the pediatric exclusivity erected any bar to FDA approval of generic versions of Depakote®. Accordingly, FDA immediately and finally approved several such generic products, including Banner's product (marketed under the trade name Stavzor™). (*See* Ex. A (Printout from the FDA's Website).) In a recent press release,

Banner announced that it has partnered with Noven Pharmaceuticals, which will market and sell Stavzor™ through its subsidiary, Noven Therapeutics. (*See* Ex. B (Banner Press Release).) Noven, in turn, announced that it expects Stavzor™ "to be in pharmacies in the latter half of August." (*See* Ex. C (Noven Press Release).) Thus, the product at issue in this litigation will be on the shelves in a matter of weeks.

Given the expiry of the patents, Abbott contacted Banner and proposed that the parties stipulate to dismissal of this entire case as moot. Banner refused. As a result, on July 28, 2008, Abbott moved for voluntary dismissal of all claims in its complaint, with prejudice. (*See* Motion for Voluntary Dismissal (D.I.18).)

IV. LEGAL STANDARD

An Article III court has subject-matter jurisdiction over an action seeking a declaratory judgment only where "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Md. Cas. Co. v. Pac. Coal & Oil Co*, 312 U.S. 270, 272 (1941); *see also* 28 U.S.C. § 2201(a) (a court may only "declare the rights and other legal relations of any interested party seeking such declaration" in "a case of actual controversy"). It is not enough that an actual controversy be present at the time of filing – a claimant bears the burden of proving that "jurisdiction over its declaratory judgment action existed at, and has continued since, the time the [claim] was filed[.]" *Sierra Applied Sci., Inc. v. Advanced Energy Indus.*, 363 F.3d 1361, 1373 (Fed. Cir. 2004).

In the realm of actions brought under the Hatch-Waxman Act, there is an additional jurisdictional wrinkle. Because there is generally no generic product on the market when these cases begin (and thus no traditional act of infringement), there would ordinarily be no subject-matter jurisdiction. To allow for the prompt adjudication of these generic drug disputes,

however, the drafters of the Act narrowly expanded Article III courts' jurisdiction by making it an act of infringement to file a § 505(b)(2) NDA containing a paragraph IV certification. *See* 35 U.S.C. § 271(e)(2); *see also Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007) (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (the Act creates "an act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification")). Relatedly, the Act also gave Article III courts jurisdiction over certain types of actions for declaratory judgments brought by a § 505(b)(2) applicant, provided that the application included a paragraph IV certification. *See* 21 U.S.C. § 355(c)(3)(D). Absent a paragraph IV certification, however, no justiciable controversy exists. *See id.*; *see also Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1245 (Fed. Cir. 2000) (the Act modified the patent laws such that it is not an act of infringement for a generic manufacturer to make or use a patented invention for purposes of developing and submitting an ANDA or § 505(b)(2) NDA, but filing such an application containing a paragraph IV certification is an act of infringement).

V. ARGUMENT

Banner's non-infringement counterclaim must be dismissed pursuant to Rule 12(b)(1). *First*, the Patents have expired and Banner's product has been approved, leaving no controversy about infringement for this Court to resolve. *Second*, by operation of law, Banner's paragraph IV certification (upon which this Court's jurisdiction was based) converted to a paragraph II certification when the Patents expired. On either ground, it is clear that this Court no longer has subject matter jurisdiction over Banner's counterclaim.

A. There Is No Longer A Justiciable Case Or Controversy Regarding Whether Banner's Now-Approved Product Infringes Abbott's Now-Expired Patents.

In its counterclaim, Banner seeks "a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of the Banner product has not infringed, does not infringe,

and will not infringe the '731 patent or the '326 patent, either directly or under the doctrine of equivalents." (Answer & Counterclaims (D.I.7).) The expiry of Abbott's Patents effectively gave Banner all of the relief that such a declaration could afford; indeed, Banner's product has now been approved by FDA. In light of these undisputed facts, Banner cannot hope to meet its "burden of proving that the facts alleged 'under all the circumstances show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Pfizer, Inc. v. Ranbaxy Labs, Ltd.*, 525 F. Supp. 2d 680, 685 (D. Del. 2007) (quoting *MedImmune Inc. v. Genetech, Inc.*, 549 U.S. 118 (2007)). To the contrary, courts uniformly recognize that when a patent expires (or is otherwise adjudged invalid or unenforceable), any previous controversy over infringement is rendered moot.

This Court faced just such a situation recently in *Pfizer*, another matter arising under the Hatch-Waxman Act. *See id.* at 686. In that case, Pfizer moved to dismiss Ranbaxy's counterclaim seeking a declaratory judgment of non-infringement on the grounds that the patent at issue had been declared invalid and Pfizer had offered Ranbaxy a covenant not to sue. *See id.* Ranbaxy argued that the Court continued to have subject-matter jurisdiction over the counterclaim because Pfizer could file for reissuance of its patent and then seek to enforce it against Ranbaxy in the future. *Id.* This Court correctly rejected that argument and dismissed the counterclaim, however, noting that the "existence of issued and *presently enforceable* patent claims against a declaratory judgment plaintiff is a necessary prerequisite to the continued litigation of the declaratory judgment action." *Id.* (emphasis added).

The Federal Circuit's recent decision in *Merck & Co. v. Apotex, Inc.*, also dooms Banner's claim. *See* 2008 WL 2753378, at *1 (July 16, 2008). There, as here, a patent holder

(Merck) filed a lawsuit pursuant to the Hatch-Waxman Act based upon the submission by a generic company (Apotex) of an application containing a paragraph IV certification. Apotex denied infringement and filed counterclaims seeking a declaratory judgment that its product would not infringe the patents and that the patents were invalid. After Merck subsequently offered Apotex a covenant not to sue on all the patents-in-suit, however, this Court granted Merck's motion to dismiss all claims and counterclaims for lack of subject-matter jurisdiction. *See id.*; *see also Merck & Co. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 424 (D. Del. 2007) ("To proceed to a substantive 'court decision' on the merits of Apotex's claims of noninfringement or invalidity would amount to an impermissible advisory opinion.") (Sleet, J.).

On appeal, the Federal Circuit affirmed, noting that the patents at issue had expired and Merck's period of regulatory exclusivity had lapsed, rendering all claims relating to the infringement or validity of the patents moot. *Merck*, 2008 WL 2753378, at *3. The court found that the only thing delaying Apotex's entry in the market at that point was a regulatory exclusivity period awarded by FDA to another generic applicant – a delay that was neither traceable to Merck nor subject to redress by a court judgment against Merck. Accordingly, the Federal Circuit confirmed that the underlying counterclaims were properly dismissed for lack of Article III jurisdiction. *Id.*

These decisions leave no doubt that Banner's non-infringement counterclaim must be dismissed. Indeed, the case for dismissal here is even more compelling, as Abbott is not merely agreeing by way of a covenant not to assert the Patents against Banner. Abbott *cannot* assert the Patents now or ever again in the future, because they have expired. Furthermore, the FDA has finally approved Banner's product. Thus, unlike Apotex in the *Merck* case, Banner no longer suffers *any* delay in entering the market. Indeed, Banner's business partner has publicly stated

that it intends to bring Stavzor™ to market before the end of the month. Going forward, any delay in the market entry of Stavzor™ can in no way be attributed to Abbott's Patents.

Ultimately, no judicially-crafted remedy stemming from a declaration of non-infringement could grant Banner relief beyond that which it has already received as a result of the expiration of the Patents. Continuing to litigate Banner's first counterclaim would do no more than waste the resources of both the Court and the parties in pursuit of, at best, an advisory opinion. This the Court should not allow. Banner's counterclaim is moot, and it should be dismissed, with prejudice.

B. Banner's Paragraph IV Certification No Longer Exists As A Matter Of Law, Thus Eliminating This Court's Subject-Matter Jurisdiction.

Dismissal is also appropriate because the paragraph IV certification submitted as part of Banner's NDA (and upon which this Court's jurisdiction was based) no longer exists. The FDA has consistently instructed that, upon expiration of a patent, a paragraph IV certification becomes a paragraph II certification, either by automatic conversion or mandatory amendment. *See e.g. Mylan Labs v. Leavitt,* 484 F. Supp. 2d 109, 120 (D.D.C. 2007) (the FDA has explained that "upon patent expiry, all ANDA applicants are presumed to have paragraph II certifications"); *Ranbaxy Labs.,* 307 F. Supp. 2d at 19 (the FDA stated that "[e]ither the applications with their Paragraph IV certifications automatically converted to Paragraph II certifications upon expiration of the patent, or Ranbaxy was required to amend them in order to reflect the patent expiry because the Paragraph IV certifications were no longer accurate").

Unlike a paragraph IV certification, inclusion of a paragraph II certification in a § 505(b)(2) NDA does not constitute the "artificial act of infringement" necessary to sustain this Court's Article III jurisdiction over what is otherwise an inchoate dispute. *Bayer*, 212 F.3d at 1245 (noting that while the submission of an application generally is not an act of infringement,

submitting an application containing a paragraph IV certification is); *see also Teva*, 482 F.3d at 1344 (a "justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents"). By operation of law, therefore, the elimination of Banner's paragraph IV certification deprives this Court of jurisdiction and compels the dismissal of Banner's non-infringement counterclaim.

VI. CONCLUSION

For the reasons set forth above, Banner's first counterclaim fails as a matter of law, and should be dismissed, with prejudice, under Federal Rule of Civil Procedure 12(b)(1).

Dated: August 8, 2008

Respectfully submitted,

CONNOLLY BOVE LODGE & HUTZ LLP

By: */s/ Paul E. Crawford*
Paul E. Crawford
DE State Bar 0493
E-mail: pcrawford@cblh.com
CONNOLLY BOVE LODGE & HUTZ LLP
1007 N. Orange St.
P.O. Box 2207
Wilmington, DE 19899
(T) 302.658.9141
(F) 302.658.5614

Attorneys for Abbott Laboratories

Of Counsel
Daniel E. Reidy; Bar No. 2306948
E-mail: dereidy@jonesday.com
James R. Daly; Bar No. 6181714
Email: jrdaly@jonesday.com
Jason G. Winchester; Bar No. 6238377
Email: jgwinchester@jonesday.com
Melissa B. Hirst; Bar No. 6282498
Email: mbhirst@jonesday.com
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601-1692
(T): 312.782.3939
(F): 312.782.8585

Perry C. Siatis
ABBOTT LABORATORIES
100 Abbott Park Road
Abbott Park, Illinois 60064-6034

Exhibit A

Drug Details

Drug Name(s)	STAVZOR (Brand Name Drug)
FDA Application No.	(NDA) 022152
Active Ingredient(s)	VALPROIC ACID
Company	BANNER PHARMACAPS
Original Approval or Tentative Approval Date	July 29, 2008
Chemical Type	3 New formulation
Review Classification	S Standard review drug

- There are no Therapeutic Equivalents
- Approval History, Letters, Reviews, and Related Documents
- Label Information

Products on Application (NDA) #022152

Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Cod
STAVZOR	VALPROIC ACID	125MG	CAPSULE, DELAYED RELEASE; ORAL	Prescription	TBD	TBD
STAVZOR	VALPROIC ACID	250MG	CAPSULE, DELAYED RELEASE; ORAL	Prescription	TBD	TBD
STAVZOR	VALPROIC ACID	500MG	CAPSULE, DELAYED RELEASE; ORAL	Prescription	TBD	TBD

Exhibit B

For More Information:
Steve Sensoli, Executive Director
Global Business Development
Banner Pharmacaps Inc.
1-336-812-7021
scsensoli@banpharm.com

BANNER®

FOR IMMEDIATE RELEASE

Banner Pharmacaps Receives FDA Approval for Valproic Acid Delayed Release Softgel Capsules

High Point, North Carolina (July 30, 2008) – Banner Pharmacaps Inc., a leader in the pharmaceutical industry for the development of soft gelatin dosage form technology, today announced that the US Food & Drug Administration (FDA) has granted final approval for the Company's New Drug Application (NDA) for Valproic Acid Delayed Release soft gelatin capsules in the 125 mg, 250 mg, and 500 mg strengths. This drug is approved for use in the treatment of manic episodes associated with bipolar disorder, as monotherapy and adjunctive therapy in multiple seizure types, and for prophylaxis of migraine headaches. It has a similar pharmacokinetic profile to Abbott Laboratories Depakote® delayed release tablets. Banner has partnered with Noven Pharmaceuticals, Inc., who will market and sell this product under the brand name of Stavzor™ through its Noven Therapeutics subsidiary.

Stavzor is the first pharmaceutical product to utilize Banner's patent-pending EnteriCare™ technology. This innovative concept allows for the direct delivery of the active pharmaceutical ingredient without encountering the challenges typical to enteric coated softgels. With EnteriCare, the enteric features reside within the shell; thereby avoiding the propensity of coated softgels to crack and chip, potentially compromising the integrity of the functional coating.

Important Product Safety Information

Valproate products should not be administered to patients with hepatic disease or significant hepatic dysfunction. Hepatic failure resulting in fatalities has occurred in patients receiving valproic acid and its derivatives, usually during the first six months of treatment. Valproate may produce teratogenic effects in the offspring of women receiving the drug during pregnancy. Benefits of valproate should be weighed against risk of injury to the fetus in women of childbearing potential.

For More Information:
Steve Sensoli, Executive Director
Global Business Development
Banner Pharmacaps Inc.
1-336-812-7021
scsensoli@banpharm.com

Cases of life-threatening pancreatitis, some rapidly progressing to death, have been reported in both adults and children receiving valproate. Valproate is contraindicated in patients with known urea cycle disorders (UCD), a group of uncommon genetic abnormalities, due to reports of sometimes-fatal cases of hyperammonemic encephalopathy. Concomitant administration of valproic acid and topiramate has been associated with hyperammonemia with and without encephalopathy.

The frequency of adverse effects, particularly elevated liver enzymes and thrombocytopenia, may be dose-related. Multi-organ hypersensitivity reactions have been reported after the initiation of valproate therapy. In a clinical trial of valproate in elderly patients with dementia, some patients taking valproate experienced somnolence, sometimes requiring discontinuation.

Common adverse events (greater than 5 percent incidence) associated with valproate in clinical studies were nausea, somnolence, dizziness, vomiting, asthenia, abdominal pain, dyspepsia, rash, diarrhea, increased appetite, tremor, weight gain, back pain, alopecia, headache, fever, anorexia, constipation, diplopia, amblyopia/blurred vision, ataxia, nystagmus, emotional lability, thinking abnormal, amnesia, flu syndrome, infection, bronchitis, rhinitis, thrombocytopenia, ecchymosis, peripheral edema, insomnia, nervousness, depression, pharyngitis, dyspnea and tinnitus.

About Banner Pharmacaps Inc.

Banner Pharmacaps Inc. is a global drug delivery and specialty pharmaceutical company which is developing a proprietary portfolio of unique products and oral dosage forms that include the enhanced technologies of enteric and controlled release softgels, as well as Soflet® Gelcaps. Headquartered in High Point, North Carolina, Banner is committed to the research, development, and manufacture of quality healthcare products to serve our global community. Additional information about Banner is available at http://www.banpharm.com.

The parent company of Banner is VION N.V., an international food group that produces high-quality foodstuffs and ingredients for humans and animals. VION has annual sales in excess €7 Billion, with 16,200 employees worldwide. The head office of VION is in Son en Breugel, The Netherlands.

For More Information:
Steve Sensoli, Executive Director
Global Business Development
Banner Pharmacaps Inc.
1-336-812-7021
scsensoli@banpharm.com

About Noven Pharmaceuticals:

Noven Pharmaceuticals, Inc.(Nasdaq: NOVN) is a specialty pharmaceutical company engaged in the research, development, manufacture, marketing and sale of prescription pharmaceutical products. Noven's business and operations are focused in three principal areas – transdermal drug delivery, the Novogyne joint venture, and Noven Therapeutics, Noven's specialty pharmaceutical unit. For more information about Noven, visit www.noven.com.

Contact:

Banner Pharmacaps Inc.

Steve Sensoli, Executive Director, Global Business Development, +1-336-812-7021

###

Exhibit C

Stavzor™ (valproic acid delayed release capsules)

Stavzor™ is part of the psychiatry products franchise of Noven Therapeutics, LLC. Stavzor™ is approved for the treatment of manic episodes associated with bipolar disorder, as monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizures, and for prophylaxis of migraine headaches.

Stavzor™ soft gel capsules are small (up to 40% smaller than Depakote® and Depakote ER® tablets at the 500 mg dosage strength) and easy to swallow, with an advanced enteric technology designed to reduce reflux and gastric irritability. The product was approved by the FDA on July 29, 2008, and it is expected to be available in pharmacies in the latter half of August.

Depakote® and Depakote ER® are registered trademarks of Abbott Laboratories.

For additional information, visit www.stavzor.com.

For full prescribing information on Stavzor™, click here.

Important Safety Information You Should Know About STAVZOR™

Liver problems Your doctor should check your liver function before you start taking STAVZOR™ and at frequent intervals while you're on therapy. If you feel generally ill (malaise), weak, and tired, if your face is swollen and you lose your appetite, and start vomiting, call your doctor immediately.

Pregnancy: Birth defects Women who can become pregnant need to know that valproic acid has been associated with birth defects, in particular with spina bifida, a condition in which the baby's spinal canal fails to close. If you are planning to become pregnant, you should discuss the risks of birth defects, along with other possible treatment options, with your doctor. If you do become pregnant while taking STAVZOR™, call your doctor immediately.
Read more important safety information about pregnancy.

Pancreatitis Some people taking valproate have experienced a serious, life-threatening illness called pancreatitis (inflamed pancreas). If you experience stomach pain, nausea, vomiting, and/or loss of appetite, call your doctor immediately.

Common side effects reported in studies with valproate were nausea, drowsiness, vomiting, and dizziness. These are not all the side effects that may occur. You will find a complete list of side effects in the full **Prescribing Information.**

For patient, physician and pharmacist inquiries regarding Stavzor™, please contact:

Kendle International, Inc.
441 Vine Street
Suite 1200
Cincinnati, Ohio 45202
Attn: Safety Department
Ph: 800-455-8070

CERTIFICATE OF SERVICE

I hereby certify that, on August 8, 2008, a true and correct copy of the foregoing documents, entitled **Brief in Support of Abbott's Motion to Dismiss Banner's First Counterclaim**, were served on the following persons via the following methods:

VIA ELECTRONIC MAIL
Charles J. Raubicheck
FROMMER, LAWRENCE & HOAG LLP
745 Fifth Avenue
New York, NY 10151
craubicheck@flhlaw.com

VIA HAND DELIVERY AND E-MAIL
George Pazuniak
Anna Martina Tyreus
WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
222 Delaware Avenue, Suite 1501
Wilmington, DE 19801
gpazuniak@wcsr.com
mtyreus@wcsr.com

/s/ Paul E. Crawford
Paul E. Crawford, Esquire (#493)
pcrawford@cblh.com